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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/766,857	LEWIS ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17 and 34-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-17 and 34-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 16-17 and 34-48 are pending. Applicants previously cancelled claims 1-15 and 18-27. Applicants have newly cancelled claims 28-33. Applicants have amended claim 16 to recite that the active material is selected from a group of drugs consisting of salbutamol (i.e. albuterol), salts of salbutamol, beclomethasone dipropionate, ipratropium bromide, and combinations thereof. Receipt and consideration of Applicants' new IDS, amended claim set, and Dr. Brambilla's declaration filed under 37 CFR 1.132, and arguments/remarks submitted on November 30, 2007 are acknowledged. Applicants' claim amendments have necessitated new grounds of rejection (e.g. under 35 USC § 103(a)).

Moot Rejections/objections

All rejections and/or objections of claims 28-33 cited in the previous office action mailed on July 3, 2007 **are moot**, because said claim(s) has/have been cancelled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 16-17 under 35 U.S.C. 102(b) as being anticipated by McNally et al. (U.S. Patent No. 5,653,961) **is withdrawn** per Applicants' claim amendments limiting the active material to a species selected from a group of drugs consisting of salbutamol (i.e. albuterol), salts of salbutamol, beclomethasone dipropionate, ipratropium bromide, and combinations thereof.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-17, 35, 37, 39, 41, 43, 45, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. (U.S. Patent No. 5,776,432) ("Schultz").

Applicant Claims

Applicants claim an aerosol produced from a solution consisting of: (a) one or more solubilized active materials selected from a group of drugs consisting of salbutamol (i.e. albuterol), salts of salbutamol, beclomethasone dipropionate, ipratropium bromide, and combinations thereof, (b) a propellant consisting of a mixture of HFA 227 and HFA 134a in a ratio of HFA 227:HFA 134a ranging from 10:90 to 90:10, (c) ethanol, and wherein the aerosol is composed of particles which have a MMAD greater than 2 microns and a fine particle fraction of particles with a size less than 4.7 microns of at lest 40%. It is also noted that claims dependent on claim 16 utilize open, "comprising" claim language.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Schultz teaches pharmaceutical **solution aerosol formulations comprising (a) a therapeutically effective amount of beclomethasone dipropionate, (b) ethanol, and (c) 1,1,1,2-tetrafluoroethane (i.e. HFA 134a), 1,1,1,2,3,3,3-heptafluoropropane, and mixtures thereof, wherein the propellant preferably constitutes an amount from about 80-99% w/w, preferably ethanol in amounts from about 2-12% w/w, and preferably about 0.02 to about 0.6% w/w of beclomethasone dipropionate** (title; abstract; col. 1, line 60 through col. 2, line 5; col. 2, lines 19-58; claims 1-6 and 9-10). Schultz teaches that the invented formulations may be utilized to treat asthma (e.g. claim 1).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Schultz is silent as to the MMAD and fine particle fraction of aerosol particles produced from the invented aerosol solution formulations. This deficiency is obviated by the teachings of Schultz.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to a person of ordinary skill at the time of the instant invention that the aerosol solution formulations taught and suggested by Schultz could be modified to comprise both HFA 227 and HFA 134a in a ratio from 10:90 to 90:10, because Schultz suggests that mixtures of HFA 227 and HFA 134a are suitable. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Regarding the recited MMAD and fine particle fractions of the claimed aerosols, these properties would be exhibited by aerosols made from the formulations suggested by Schultz, because the formulations suggested by Schultz are substantially similar to those used by Applicants to obtain the claimed aerosols. Applicants' declaration is noted, but does not address or affect the merits of the instant rejection and is not further addressed herein. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 34, 36, 38, 40, 42, 46, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. (U.S. Patent No. 5,776,432) ("Schultz") as applied to claims 16-17, 35, 37, 39, 41, 43, 45, and 47 above, and further in view of Stefely et al. (U.S. Patent No. 6,126,919).

Applicant Claims

Applicants claim an aerosol produced from a solution as described above in the instant office action wherein the aerosol comprises as the active material, salbutamol (i.e. albuterol), salts of salbutamol, ipratropium bromide, or combinations thereof.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Schultz were set forth above in the instant office action. Stefely teaches preferred pharmaceutical formulations designed for oral/nasal inhalation, wherein the formulation comprises a drug suitable for the treatment of diseases such as asthma, COPD, etc., wherein preferred drugs include **albuterol (i.e. salbutamol), beclomethasone dipropionate, budesonide, ipratropium bromide, salts, solvates, and mixtures thereof and the formulation is preferably in the form of a solution** (col. 8, lines 40-42, 59-62; col. 9, lines 3-6 and 16-37; and claims 1-3). The formulations may be contained within a metered dose inhaler and also may

comprise a mixture of hydrofluorocarbon propellants, selected from **HFA 134a and HFA 227** (claims 1-3).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Schultz is silent as to the MMAD and fine particle fraction of aerosol particles produced from the invented aerosol solution formulations and lacks the teaching of aerosols made from HFA aerosol solution formulations wherein the active material is salbutamol (i.e. albuterol), salts of salbutamol, ipratropium bromide, or combinations thereof. These deficiencies are obviated by the teachings of Schultz and/or Stefely.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to a person of ordinary skill at the time of the instant invention that the aerosol solution formulations of Schultz could be modified to comprise in addition to or in lieu of beclomethasone dipropionate other drugs known as being suitable for the treatment of asthma, such as albuterol, ipratropium bromide, and salts, solvates, and mixtures thereof. An ordinary skilled artisan would have been motivated to add albuterol, ipratropium bromide, or salts thereof to Schultz' invented formulations or substitute beclomethasone dipropionate for one of these drugs, because albuterol, ipratropium bromide, or salts are art-recognized as being suitable for the treatment of asthma. Furthermore, an ordinary skilled artisan would have also been motivated to modify the teachings of Schultz with the teachings of Stefely concerning the active material, because both references are in the same field of endeavor,

namely aerosol solution formulations for the treatment of asthma. An ordinary skilled artisan would have had a reasonable expectation of success upon combination because Schultz and Stefely are in the same field of endeavor, and teach similar HFA propellant based aerosol solution formulations. Regarding the recited MMAD and fine particle fractions of the claimed aerosols, these properties would be exhibited by aerosols made from the formulations suggested by Schultz, because the formulations suggested by Schultz as modified with the one or more of the preferred drugs taught by Stefely are substantially similar to those used by Applicants to obtain the claimed aerosols. Applicants' declaration is noted, but does not address or affect the merits of the instant rejection and is not further addressed herein. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-17 and 34-38 (all pending claims) are rejected on the ground of nonstatutory obviousness-type double patenting of as being unpatentable over claims 1-12, 14, and 16-29 of U.S. Patent No. 6,713,047 (USPN '047) in view of Stefely et al. (U.S. Patent No. 6,126,919) (USPN '919) for the reasons of record and further articulated below.

Independent claim 16 of the instant application has been described above in the instant office action. Independent claim 1 of USPN '047 claims a hydrofluorocarbon-based solution formulation comprising essentially the same components as the formulation utilized to product Applicants' claimed aerosol, wherein the active material is selected from an anticholinergic drug, a corticosteroid, or a beta-2 agonist. The difference between the claims of USPN '047 and the instant application is that the claims of USPN '047 do not recite a specific corticosteroid (e.g. beclomethasone dipropionate), beta-2 agonist (e.g. salbutamol), or an anticholinergic (i.e. ipratropium bromide). This deficiency is cured by the teachings of USPN '919 set forth above, which demonstrates that salbutamol (i.e. albuterol), beclomethasone dipropionate, and ipratropium bromide were known drugs at the time of Applicants' invention and would have been readily recognized by an ordinary skilled artisan as belonging to the genus of corticosteroid (i.e. beclomethasone dipropionate), beta-2 agonist (i.e. salbutamol), and anticholinergic agent (i.e. ipratropium bromide). Regarding the recited MMAD and fine particle fractions of the claimed aerosols, these properties would be exhibited by aerosols made from the formulations claimed by USPN 047, because these formulations as modified with the one or more of the preferred drugs taught by Stefely are substantially similar to those used by Applicants to obtain

the claimed aerosols. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 16-17 and 34-38 (all pending claims) *prima facie* obvious over claims of claims 1-12, 14, and 16-29 of U.S. Patent No. 6,713,047 (USPN '047) in view of Stefely et al. (U.S. Patent No. 6,126,919) (USPN '919).

Claims 34-48 are rejected on the ground of nonstatutory obviousness-type double patenting of as being unpatentable over claims 1-4, 15, and 17 of U.S. Patent No. 6,716,414 (USPN '414).

Independent claim 16 of the instant application has been described above in the instant office action. The rejected dependent claims of the instant application utilize "comprising" claim language, thus broadening the "consisting of" language of claims 16-17 of the instant application. Independent claim 1 of USPN '414 claims a hydrofluorocarbon-based solution formulation comprising (i) formoterol, (ii) a liquefied HFA propellant, (iii) cosolvents selected from pharmaceutically acceptable alcohols (e.g. ethanol), and (iv) a mineral acid. Dependent claims 2-4 of USPN '414 indicate that the formulations comprise a steroid (e.g. beclomethasone dipropionate) or an anticholinergic (e.g. ipratropium bromide). Dependent claim 15 of USPN '414 indicates that the propellant comprises one or more HFAs selected from the group consisting of HFA 134a and HFA 227. Dependent claim 17 of USPN '414 indicates that the co-solvent comprises ethanol. Regarding the recited MMAD and fine particle fractions of the claimed aerosols, these properties would be exhibited by aerosols made from the formulations claimed by USPN '414, because these formulations as modified with the one or more of the preferred drugs taught by Stefely are substantially similar to those used by Applicants to obtain

the claimed aerosols. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 34-38 *prima facie* obvious over claims 1-4, 15, and 17 of U.S. Patent No. 6,716,414 (USPN '414).

Claims 34-48 are rejected on the ground of nonstatutory obviousness-type double patenting of as being unpatentable over claims 1-6, 10, and 22-24 of U.S. Patent No. 6,964,759 (USPN '759) in view of Stefely et al. (U.S. Patent No. 6,126,919) (USPN '919) for the reasons of record and further articulated below.

Independent claim 16 of the instant application has been described above in the instant office action. The rejected dependent claims of the instant application utilize "comprising" claim language, thus broadening the "consisting of" language of claims 16-17 of the instant application. Independent claim 1 of USPN '759 claims a hydrofluorocarbon-based solution formulation comprising (i) at least one solubilized quaternary ammonium compound (e.g. ipratropium bromide), (ii) at least one hydrofluorocarbon propellant, (iii) 15 % w/w or less of a cosolvent, and (iv) at least one low volatility component. The difference between the claims of USPN '759 and the instant application is that the claims of USPN '759 do not recite that the formulations may comprise beclomethasone dipropionate, salbutamol or salts of salbutamol and the formulations of USPN '759 may also comprise a low volatility component. This deficiency is cured by the teachings of USPN '919 set forth above, which demonstrates that salbutamol (i.e. albuterol), beclomethasone dipropionate, and ipratropium bromide were known drugs at the time of Applicants' invention and would have been readily recognized by an ordinary skilled artisan as belonging to the genus of corticosteroid (i.e. beclomethasone dipropionate), beta-2 agonist

(i.e. salbutamol), and anticholinergic agent (i.e. ipratropium bromide). Regarding the recited MMAD and fine particle fractions of the claimed aerosols, these properties would be exhibited by aerosols made from the formulations claimed by USPN 047, because these formulations as modified with the one or more of the preferred drugs taught by Stefely are substantially similar to those used by Applicants to obtain the claimed aerosols. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 34-38 *prima facie* obvious over claims of claims 1-6, 10, and 22-24 of U.S. Patent No. 6,964,759 (USPN '759) in view of Stefely et al. (U.S. Patent No. 6,126,919) (USPN '919).

Response to Arguments

Applicant's arguments filed November 30, 2007 have been fully considered but they are not persuasive. Applicants have traversed the above non-provisional obviousness-type double patenting rejections by asserting that there is allegedly nothing in the claims of the cited patents which would suggest Applicants' claimed aerosols. These are not substantive arguments, because these arguments fail to articulate the deficiencies allegedly present in the cited claims of the cited U.S. patents that fail allegedly fail to render the rejected claims obvious. Mere argument in the absence of evidence is unpersuasive.

The provisional rejection on the ground of nonstatutory obviousness-type double patenting of claims 16-17 as being unpatentable over claims 1, 4-7, and 13 of copending Application No. 10/505,679 **is maintained** for the reasons of record set forth on pages 4-5 of the office action mailed on October 12, 2006.

Response to Arguments

Applicant's arguments filed November 30, 2007 have been fully considered but they are not persuasive. Applicants have not traversed the instant rejection and have requested that this rejection be held in abeyance. This rejection is maintained.

Claims 16-17 and 34-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 14-16, 20-21, 3-32, and 42-44 of copending application 09/831,888 (copending '888) (now issued, but no patent number has been assigned) for the reasons of record (see office action mailed 1/18/06).

Claims 34-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24,-25, 33, and 37-41 of copending application 10/435,032 (copending '032) for the reasons of record (see office action mailed 1/18/06) and because the rejected dependent claims of the instant application utilize "comprising" claim language. Regarding the recited MMAD and fine particle fractions of the claimed aerosols, these properties would be exhibited by aerosols made from the formulations claimed by copending '032, and the rejected claims do not prohibit the inclusion of glycerol.

Claims 34-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24, 30, 33-34, 40, 45-49, and 52 of copending application 10/435,354 (copending '354) for the reasons of record (see office action mailed

1/18/06) and because the rejected dependent claims of the instant application utilize "comprising" claim language. Regarding the recited MMAD and fine particle fractions of the claimed aerosols, these properties would be exhibited by aerosols made from the formulations claimed by copending '354, and the rejected claims do not prohibit the inclusion of glycerol.

Other Matter

It is noted that a provisional rejection on the ground of nonstatutory obviousness-type double patenting of the instant application is of record in the prosecution of copending application 10/612,067. Thus, this provisional rejection has not been repeated herein.

Conclusion

Claims 16-17 and 34-48 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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